Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Health Institutions)
Director General of Health Services in all Governorates
Director of Rational Use of Medicine (MOH)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
Director of Pharmacy & Medical Stores in all Governorate (for distribution pls.)
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No.. 22 ..... dated 10/03/19. regarding FDA's decision to add Boxed Warning for increased risk of death with gout medicine Uloric (*Febuxostat*).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Supdt. of Central Drug Information
- Head of Cordn. & FU

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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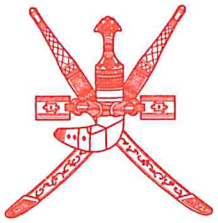

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Circular No. 22 / 2019

03 -07-1440 H
10 -03-2019

FDA adds Boxed Warning for increased risk of death with gout medicine Uloric (*Febuxostat*).

The U.S. Food and Drug Administration (FDA) has concluded there is an increased risk of death with Uloric (febuxostat) compared to another gout medicine, allopurinol. This conclusion is based on an in-depth review of results from a safety clinical trial that found an increased risk of heart-related death and death from all causes with Uloric.

As a result, FDA is updating the Uloric prescribing information to require a *Boxed Warning* and a new patient Medication Guide. FDA is also limiting the approved use of Uloric to certain patients who are not treated effectively or experience severe side effects with allopurinol.

Uloric was FDA-approved in 2009 to treat a type of arthritis called gout in adults. Gout happens when a naturally occurring substance in the body called uric acid builds up and causes sudden attacks of redness, swelling, and pain in one or more joints. Uloric works by lowering uric acid levels in the blood.

Patients should tell the health care professional if they have a history of heart problems or stroke and discuss the benefits and risks of using Uloric to treat gout. They should also seek emergency medical attention right away if they experience the following symptoms while taking Uloric:

- Chest pain
- Shortness of breath
- Rapid or irregular heartbeat
- Numbness or weakness on one side of your body
- Dizziness
- Trouble talking
- Sudden severe headache

Do not stop taking Uloric without first talking to health care professional, as doing so can worsen your gout.

Health care professionals should reserve Uloric for use only in patients who have failed or do not tolerate allopurinol. Counsel patients about the cardiovascular risk with Uloric and advise them to seek medical attention immediately if they experience the symptoms listed above.

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ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
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The results showed that overall, Uloric did not increase the risk of these combined events compared to allopurinol. However, when the outcomes were evaluated separately, Uloric showed an increased risk of heart-related deaths and death from all causes. In patients treated with Uloric, 15 deaths from heart-related causes were observed for every 1,000 patients treated for a year compared to 11 deaths from heart-related causes per 1,000 patients treated with allopurinol for a year. In addition, there were 26 deaths from any cause per 1,000 patients treated for a year with Uloric compared to 22 deaths per 1,000 patients treated for a year with allopurinol. This safety trial was also discussed at a public Advisory Committee meeting of outside experts on January 11, 2019.

Febuxostat is registered in Oman in the brand name Adenuric 120mg & 80mg.

The healthcare professionals are kindly requested to report any adverse events or side effects associated with the use of the above product or any other medicinal product to the Department of Pharmacovigilance & Drug Information in DGPA&DC.

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIR & DRUG CONTROL

dg-padc@moh.gov.om : البريد الإلكتروني ٢٢٣٥٨٤٨٩ – فاكس: ٢٢٣٥٧١١١ – هاتف: ١٠٠ – الرمز البريدي: ٣٩٣ مسقط – ص . ب:
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